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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/040,485	03/17/98	RADOSEVICH J	8998/3

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ALICE O. HARTIN
BARNES & THORNBURG
200 WEST MADISON STREET
SUITE 2610
CHICAGO IL 60610

EXAMINER	
BURKE, J	

ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 11/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/040,485	Radosevich et al
Examiner	**Group Art Unit**
Julie E. Burke, (Reeves), Ph.D.	1642

☒ Responsive to communication(s) filed on *10 Sep 1999* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) *1-5, 8, and 12-18* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *6, 7, 9-11, 19, and 20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group II, claims 6, 7, 9-11 in Paper No. 13 is acknowledged.

2. Claims 1-5, 8, and 12-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

3. Claims 19-20 have been added. Claims 6-7, 9-11 have been amended. Claims 1-20 are pending. Claims 6-7, 9-11 and 19-20 are under examination.

4. The text of those sections of Title 35, U.S.C. Code not included in this Office Action can be found in a prior Office Action.

5. The following Office Action contains some NEW GROUNDS of rejection.

Claim Rejections - 35 U.S.C. § 101

6. The rejection of Claims 6, 7, 9, 10, and 11 under because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment(s) to the claims.

Claim Rejections - 35 U.S.C. § 112

7. The rejection of Claims 6, 7, 9, 10, and 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, by reciting "segment.", "claim 1" and "claim 2", "amino acid sequence," is withdrawn in view of the amendment(s) to the claims.

8. The rejection of Claims 6, 7, 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for failing to recite SEQ ID NO:s is withdrawn in view of the amendment(s) to the claims.

9. The rejection of Claim 11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for failing to recite SEQ ID NO:s is made again and maintained.

a. The response set forth on page 3 has been considered carefully but is deemed not to be persuasive. The response argues that the claims have been amended to recite SEQ ID NO:, however claim 11 still contains a sequence without a SEQ ID NO:. It is noted that the sequence present in claim 11 consists of amino acid residues 3-8 of SEQ ID NO: 8. Amending the claim to recite such would be sufficient to obviate this rejection.

b. The rejection of Claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment(s) to the claims. However, in view of the amendment to the claims, the following new grounds of rejection have been made.

10. Newly amended Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim has been amended to recite "a cDNA molecule that specifically hybridizes to the nucleotide sequence set forth in Fig 1 (SEQ ID NO:1). This claim is indefinite for the following two reasons.

a. First, the term "sequence" refers to information describing the nucleic acid or amino acid sequence. Information is not a chemical structure, therefore, it is not clear how "sequences" can specifically hybridize to the cDNA molecule. Replacing this term with polynucleotide, DNA, RNA, as appropriate, may be sufficient to obviate this rejection.

b. Second, the claim is indefinite for reciting "specifically hybridizes" because it is not clear what conditions are encompassed by the phrase "specifically hybridizes". As written, it is impossible for one skilled in the art to determine the metes and bounds of the claims.

11. Newly amended Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Claim 7 has been amended to recite "cDNA molecule that specifically hybridizes". The response fails to point to where the specification provides support for the amendment. It is noted that the phrase 'specifically hybridizes" is not typically used to refer to hybridization conditions. Applicant is required to either point to where the specification provides support for the phrase or to remove it from the claims.

12. Newly amended Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Evidence that claim 7 fail(s) to correspond in scope with that which applicant(s) regard as the invention can be found in Paper No. 13 filed 9/10/99. In that paper, applicant has stated that the claim is amended to include cDNA molecules that t hybridize to a molecule having SEQ ID NO: 1 under stringent conditions, and this statement indicates that the invention is different from what is defined in the claim(s) because claim 7 does not recite "stringent conditions".

13. Newly amended Claim 7 is rejected as not being commensurate in scope with the specification because these claims recite any DNA molecule that can specifically hybridize to a molecule of SEQ ID NO: 1. "Specifically hybridizing" polynucleotides may include various mutations, deletions, insertions and fusion proteins of the encoded protein. Since the specification

has not identified which amino acids or nucleic acid sequences are critical or essential characteristics of the protein consisting of SEQ ID NO: 2 encoded by SEQ ID NO 1, there is a lack of sufficient guidance to determine which amino acids substitutions or protein domain alterations or mRNA sequence changes could be made without altering the fundamental characteristics of the protein consisting of SEQ ID NO: 2 and there are no insufficient working examples of any such variants. Since the state of the art of protein modification suggests that the effects of sequence alterations are unpredictable and since the specification provides no guidance as to which changes would result in an active protein, undue experimentation would be required to determine which specifically hybridizable DNAs would encode an authentic cDNA of SEQ ID NO: 1 or protein of SEQ ID NO: 2 with all its identifying characteristics.

Moreover, the specification fails to recite under what hybridizing conditions the claimed DNA would anneal to the cDNA of SEQ ID NO: 1. Under low stringency conditions, it would be expected that a wide variety of unrelated DNA molecules would be able to anneal to the cDNA of SEQ ID NO: 1. The specification is silent concerning the washing conditions, molarity of the salt, degree of temperature and length of the incubations that result in the hybridization. In absence of such guidance and/or working examples, one skilled in the art would reasonably conclude that a large number of DNA molecules would be able to hybridize, however, the specification has not taught how all the hybridizing molecules would be cDNAs capable of encoding a protein equivalent to that of SEQ ID NO: 2.

14. Claim 9 and newly amended and newly added claims 6, 7, 10, 11, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to "a molecule having an amino acid sequence", "fragments." and newly added phrases "a nucleotide sequence as shown in FIG 1" and "molecule with an amino acid sequence".

A "molecule having an amino acid sequence", "fragments" and "molecule with an amino acid sequence". includes proteins and peptides that have peptide backbones and side-chains, as well as protein-nucleic acid hybrid molecules, that have nucleic acid backbones and amino acid side chains. The term "having" is defined as "to have in whole or in part." It is therefore unclear whether applicant is claiming a sequence defined by a specific SEQ ID NO or a fragment of that sequence.

Deleting the phrase "a molecule having", "fragments" and "molecule with an amino acid sequence" and replacing it with "a molecule comprising of" or "a molecule consisting of" (as appropriate) would obviate this rejection. The response has apparently not specifically addressed this rejection.

15. The rejection of Claims 9-11 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is made gain and maintained. The claims are drawn to sequences that are defined by single letter designations (e.g. APPEDNPVED) for each amino acid. 37CFR 1.821-1.825

state that amino acid sequences must be claimed and disclosed by using 3 letter designations well known in the art. Further, only the specific SEQ ID NO designations are necessary in order to claim the sequence.

Defining all claimed sequences in terms of only their SEQ ID NO designations would obviate this rejection. The response has apparently not specifically addressed this rejection.

16. Claim 9 stand indefinite as being structured as an improper Markush claim, by reciting the format "consisting of the group A, B, C, D, and E or F." Proper Markush claims are in the following format: "X is selected from a group consisting of A, B, C, and D" or "the X is A, B, C or D." (See MPEP 2173.05 (h)). It is noted that claim 9 is written in the format of "selected from the group consisting of A, B, C, D and E, and any fragment or combinations thereof". Amending the claim to recite the format "Selected from the group consisting of A, B, C, D, E, any fragment and combinations thereof" would be sufficient to obviate this rejection. The fact remains that the claim is indefinite and it is not clear whether the newly added amendment "that is immunologically active" refers to the all the peptides, fragments and combinations, or wether this phrase refers only to the final item "combinations". The response states that the claims have been amended to correct the Markush group of Claim 9, however no such amendment has been found.

Claim Rejections - 35 U.S.C. § 102

17. Claim 9 stands rejected under 35 U.S.C. 102(b) as being anticipated by Hodges et al (US Patent 5,223,604). The claim is drawn to a vaccine comprising a fragment of the peptides defined by SEQ ID NOS:6, 7, 8, or 9.

Given its broadest possible scope, a fragment of the claimed sequence comprises a single amino acid. Proline comprises a fragment of the claimed sequences. Hodges et al teach a vaccine comprising a peptide (SEQ ID NO:2 in Hodges et al) containing a proline residue. Therefore, Hodges et al teaches a vaccine comprising a fragment of the claimed sequences. The response set forth on page 3 has been considered carefully but is deemed not to be persuasive. The response argues that the fragment would necessarily have to be immunologically active, however it is not clear (1) whether this newly added phrase refers only to the combinations and not to the fragments and (2) what is meant by the term "immunologically active". The response argues that the an epitope is slightly smaller that about 6-7 amino acids and that an epitope is needed for an active vaccine, therefore a size of one amino acid is not suitable. The claim recite the open claim language a "vaccine comprising" which allows addition for other elements, including additional peptides or additional amino acids on the fragment taught by Hodges. Furthermore, the claims are not limited to epitopes or active vaccines. In view of the indefinite claim language, the rejection has been made again and maintained. Also, Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims. Arguments presented that rely on particular distinguishing features are not persuasive where those features are not recited in the claims.

18. Newly amended Claims 6, 7, 9, 10-11 and newly added claim 20 stands rejected under 35 U.S.C. 102(b) as being anticipated by Korioth et al (Gene 150:395-399 (1994)). The newly amended claims are drawn to an isolated amino acid molecule having an amino acid sequence SEQ ID NO:6 or SEQ ID NO:8, fragments thereof.

a. As set forth above, the newly added term "having" is open claim language and reads upon variants and fragments and larger molecules which contain SEQ ID NO: 6, for example.

b. Korioth et al teach an amino acid sequence comprising SEQ ID NO:6 (page 396, Figure 1, amino acids 281-290) and SEQ ID NO:8 (page 396, Figure 1, amino acids 173-182). The in vitro translated products shown in Fig 3 meet the limitation of an isolated molecule. The response set forth on page has been considered carefully but is deemed not to be persuasive. The response argues that Korioth et al"s molecule is not isolated. This is not persuasive because the molecular weight separation shown in Fig 3 demonstrates the isolation of the protein from other proteins which have different apparent molecular weights.

c. Amended the claims to recite

"Isolated molecule consisting of the amino acid sequence encoded by a cDNA molecule with a nucleotide sequence consisting of SEQ ID NO: 1" (Claim 6)

"A vaccine comprising an isolated molecule consisting of an amino acid sequence selected from the group consisting of sequence encoded by SEQ ID NO: 1, protein of SEQ ID NO: 2, peptides consisting of SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, immunogenic peptide fragments thereof and combinations thereof" (claim 9, dependent, of course, upon support in the specification as originally filed for "immunogenic fragments")

"isolated molecule consisting of the amino acid sequence selected from the group consisting of SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO:, 8 and SEQ ID NO: 9" (claim 10) and

"isolated molecule consisting of amino acid residues of 3 to 8 of SEQ ID NO: 8" (claim 11) and

"Isolated molecule consisting of SEQ ID NO: 2" (claim 20)

would be sufficient to obviate this rejection.

19. Claims 6, 7, 9, 10-11, 19 and 20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Jia et al (J. Biol. Chem. 267:14322-14327 (1992)).

Jia et al teach an amino acid sequence comprising SEQ ID NO:9 (page 14324, Figure 2, amino acids 248-257). Newly amended claim 10 reads upon fragments of SEQ ID NO: 9 because of the open claim language "having". The newly amended claims now recite "isolated" however, the gel electrophoresis shown in Fig 4 of Jia et al is evidence of isolation of the protein away from other proteins having different apparent molecule weights. Similarly, the other newly amended claim also read upon fragments and protein comprising the fragments so the rejection has been made again and maintained. The response set forth on page 3 has been considered carefully but is deemed not to be persuasive. The response argues that similar to that set forth for the rejection of Korioth. Making the suggested amendments to the claims as set forth above n the preceding rejection would be sufficient to obviate this rejection.

Conclusion

20. No claim is allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie E. Burke, née Reeves, Ph.D, whose telephone number is (703) 308-7553. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

23. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Julie E. Burke, née Reeves, Ph.D.

Primary Patent Examiner

(703) 308-7553

JULIE BURKE
PRIMARY EXAMINER